K062256

FEB 26 2007

510(k) SUMMARY

For

Hill Laboratories

HF54 Combination Ultrasound Interferential and Premodulated Stimulation System

1. Submitter's Name and Address

Submitter's Name:	Hill Laboratories
Address:	3 Bacton Hill Rd
City, State, and Zip:	Frazer, PA 19355

2. Contact Person

Name:	Brady Aller
Title:	Sales/Service Manager
Telephone:	(610) 644-2867
Facsimile:	(610) 647-6297
E-mail:	bradyaller@hilllabs.com

3, Manufacturing Facility Address

Manufacturer:	Hill Laboratories
Address:	3 Bacton Hill Rd
City, State, and ZIP:	Frazer, PA 19355

4. Establishment Registration Number

Establishment Registration Number:	2510425

5. Reason for Submission

New Device

6. New Device Details

Proprietary or Trade Name:	HF54 Combination Ultrasound Interferential and Premodulated Stimulation System
Common Name:	Ultrasonic Diathermy

7. Device Common Name, Classification, Product Code & CFR No.

Common Name	Class	ProCode	CFR
Ultrasonic Diathermy	2	IMI	890.5300
Interferential Current Therapy	2	LIH	
Infrared lamp	2	ILY	890.5500

8. Classification Name

diathermy, ultrasonic, for use in applying therapeutic deep heat

interferential current therapy

lamp, infrared, therapeutic heating

9. Device Classification Panel

Physical Medicine & Neurology

10. Indications for Use

10.1 Interferential and Premodulated Modes

Pain relief for:

Symptomatic relief of chronic intractable pain and/or management of traumatic or post surgical pain.

10.2 Ultrasound Therapy

Ultrasound therapy is available from the HF54 and indicated for:

Applying therapeutic deep heat within body tissues for the treatment of selected chronic and sub-chronic medical conditions such as:

Relief of pain

Muscle Spasms

Joint contractures

The combination ultrasound & electrotherapy modes offer deep heat for pain management (ultrasound therapy) at the same time that electrical stimulation for either pain management or muscle stimulation is being delivered. Two electrotherapy modes utilizing Premodulated IFC can be utilized at a time in conjunction with the ultrasound mode. These are using one or two ultrasound applicators. The second ultrasound applicator is optional.

The intended Use/Indications For Use stated herein are consistent with the cleared indications for use for the predicate devices.

10.3 Infrared Therapy

An Infrared light probe is available as an optional accessory (HF023) for use with the Hill Laboratories HF54 Combination Ultrasound Interferential and premodulated stimulation system or with an optional external medical grade, isolated power supply. It is used to provide topical heating for:

- Temporary increases in local blood flow and circulation
- Temporary relief of minor muscle and joint aches
- Temporary relief of pain and stiffness
- Relaxation of muscles
- Temporary relief (or relaxation) of muscle spasms
- Temporary relief of minor pain and stiffness associated with arthritis

11. Standards

11.1 Mandatory Standards

21 CFR 1050.10 is applicable to therapeutic ultrasound. The HF54 Combination Ultrasound Interferential and Premodulated Stimulation System complies with this mandatory standard.

11.2 Consensus Standards

The HF54 Combination Ultrasound Interferential and Premodulated Stimulation System is designed to comply with the following Consensus Standards:

STANDARD NO.	TITLE
IEC 60601-1 +A1, +A2	Medical Electrical Equipment- Part 1: General Requirements for Safety
UL 60601-1	Medical Electrical Equipment- Part 1: General Requirements for Safety
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-2-5	Medical electrical equipment - Part 2-5: Particular requirements for the safety of ultrasonic physiotherapy equipment
IEC 60601-2-10	Medical electrical equipment. Part 2: Particular requirements for the safety of nerve and muscle stimulators

12. Predicate Devices

510(k) Number	*Trade or Proprietary or Model Name*	*Manufacturer*	*Class*
K031329	Solaris Model 708 and 709	Dynatronics	2

12.1 Substantial Equivalence (SE) Rationale

The HF54 offers electrical stimulation, ultrasonic therapy and/or combination of the two and shares the same or similar basic characteristics including waveforms, operating frequencies and the same use in physical medicine and neurology as the predicate device. The new device and the predicate device are intended to be used by a qualified therapist.

The light wavelengths (visible and infrared) and output intensities for the HF023 Infrared therapy probe are the same as the predicate device's Infrared therapy probe cleared under K031239.

The methods of application and intended use/indications for use are the same and the same patient population is intended to be treated by the new device and the predicate device.

The ultrasound output and electrical stimulation currents are consistent with FDA guidance and international standards. The predicate device claims compliance to the same standards.

The materials used in construction of the device and the method of information display are similar. The measured parameters for the proposed HF54 are the same as those displayed on the predicate devices.

12.2 Conclusion

The proposed HF54 including HF023 Infrared Therapy probe is Substantially Equivalent to the Dynatronics Solaris device cleared under K031329.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Hill Laboratories
% Mr. Brady Aller
Sales/Service Manager
3 Bacton Hill Road
Frazer, Pennsylvania 19355

FEB 26 2007

Re: K062256
Trade/Device Name: HF54 Combination Ultrasound Interferential and Premodulate
Regulation Number: 21 CFR 890.5300
Regulation Name: Ultrasonic diathermy
Regulatory Class: Class II
Product Code: IMI, ILY, LIH
Dated: January 8, 2007
Received: January 10, 2007

Dear Mr. Aller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0210 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) No.
If known _____

Indications For Use statement – Interferential and Premodulated Modes

Device Name: HF54 Combination Ultrasound Interferential and Premodulated Stimulation System

Indications For Use:

The HF54 is indicated for:

Pain relief for:

Symptomatic relief of chronic intractable pain and/or management of traumatic or post surgical pain.

Continued on next page

Prescription Use (Per 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (Per 21 CFR 801 Subpart C)	____

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for MKM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062256

510(k) No.
If known _____

Indications For Use statement – Ultrasound Therapy

Device Name: HF54 Combination Ultrasound Interferential and Premodulated Stimulation System

Indications For Use:

Ultrasound therapy is available from the HF54 and indicated for:

Applying therapeutic deep heat within body tissues for the treatment of selected chronic and sub-chronic medical conditions such as:

Relief of pain

Muscle Spasms

joint contractures

The combination ultrasound & electrotherapy modes offer deep heat for pain management (ultrasound therapy) at the same time that electrical stimulation for either pain management or muscle stimulation is being delivered. Two electrotherapy modes utilizing Premodulated IFC can be utilized at a time in conjunction with the ultrasound mode. These are using One or two ultrasound applicators. The second ultrasound applicator is optional.

Continued on next page

Prescription Use (Per 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (Per 21 CFR 801 Subpart C)	____

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) No.
If known _____

Indications For Use statement –Infrared Applicator

Device Name: Infrared Therapy (using optional HF023)

Indications For Use:

An Infrared Therapy Probe is available as an optional accessory (HF023) for use with the Hill Laboratories HF54 Combination Ultrasound Interferential and premodulated stimulation system or for stand-alone use with an optional external medical grade, isolated power supply. It is used to provide topical heating for:

- Temporary increases in local blood flow and circulation
- Temporary relief of minor muscle and joint aches
- Temporary relief of pain and stiffness
- Relaxation of muscles
- Temporary relief (or relaxation) of muscle spasms
- Temporary relief of minor pain and stiffness associated with arthritis

Prescription Use (Per 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (Per 21 CFR 801 Subpart C)	_____

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)